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8 UNITED STATES DISTRICT COURT
9 SOUTHERN DISTRICT OF CALIFORNIA
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11 KENTON L. CROWLEY, *et al.*,
12 Plaintiffs,
13 v.
14 EPICEPT CORPORATION, *et al.*,
15 Defendants.
16

Civil No. 09-CV-0641-L(BGS)

**ORDER GRANTING MOTION
TO EXCLUDE [DOC. 127]**

17
18 Pending before the Court is Defendant's motion to exclude Plaintiffs' expert Mr.
19 Pedersen's purported expert opinions. The Court has held oral argument on the matter.
20 For the following reasons, and as indicated below, the Court **GRANTS** the motion and
21 excludes Mr. Pedersen's testimony and expert report from the proceedings.
22

23 **I. BACKGROUND**

24 On March 5, 2015, Defendant filed a motion to exclude the testimony and expert
25 report of Plaintiffs' only damages expert, Chris Pedersen. On March 9, 2015, Plaintiffs
26 opposed this motion. On March 10, 2015, this Court conducted a *Daubert* hearing on
27 this issue.

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1 II. LEGAL STANDARD

2 Federal Rule of Evidence 702 provides that:

3 A witness who is qualified as an expert by knowledge, skill, experience, training,
4 or education may testify in the form of an opinion or otherwise if:

5 (a) the expert's scientific, technical, or other specialized knowledge will
6 help the trier of fact to understand the evidence or to determine a fact in
7 issue;

8 (b) the testimony is based on sufficient facts or data;

9 (c) the testimony is the product of reliable principles and methods; and

10 (d) the expert has reliably applied the principles and methods to the facts of
11 the case.

12 Fed. R. Evid. 702.

13 Before allowing the jury to hear expert testimony, a district court must carry out its
14 gatekeeping role to determine whether the expert testimony is admissible under Federal
15 Rule of Civil Procedure 702. *See Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457,
16 464–65 (9th Cir. 2014) (en banc). An expert witness may testify at trial if the expert’s
17 “specialized knowledge will help the trier of fact to understand the evidence or to
18 determine a fact in issue.” Fed. R. Evid. 702(a). A witness must be “qualified as an
19 expert by knowledge, skill, experience, training, or education” and may testify if (1) “the
20 testimony is based on sufficient facts or data,” (2) “the testimony is the product of
21 reliable principles and methods,” and (3) “the expert has reliably applied the principles
22 and methods to the facts of the case.” Fed. R. Evid. 702(b-d); *see also Kumho Tire Co.,*
23 *Ltd. v. Carmichael*, 526 U.S. 137, 141, 148–49 (1999). Expert testimony is liberally
24 admitted under the Federal Rules. *See Daubert*, 509 U.S. at 588 (noting that Rule 702 is
25 part of the “liberal thrust of the Federal Rules and their general approach of relaxing the
26 traditional barriers to opinion testimony”); *see also* Fed. R. Evid. 702 Advisory
27 Committee Notes to 2000 Amendments (“[R]ejection of expert testimony is the
28 exception rather than the rule.”).

1 The Ninth Circuit has interpreted Rule 702 to require that “expert testimony be
 2 both relevant and reliable.” *Barabin*, 740 F.3d at 463 (internal quotation marks and
 3 alterations omitted). “Relevancy simply requires that ‘[t]he evidence ... logically advance
 4 a material aspect of the party’s case.’” *Id.* (alterations in original) (quoting *Cooper v.*
 5 *Brown*, 510 F.3d 870, 942 (9th Cir. 2007)). As to reliability, the district court must
 6 determine whether an expert’s testimony has “a reliable basis in the knowledge and
 7 experience of the relevant discipline.” *Kumho Tire*, 526 U.S. at 149 (internal quotation
 8 marks and alterations omitted). “The focus, of course, must be solely on principles and
 9 methodology, not on the conclusions that they generate.” *Daubert*, 509 U.S. at 595; *see*
 10 *also Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010).

11 In *Daubert* and *Kumho Tire*, the Supreme Court identified the following factors a
 12 court should use to determine whether the methods and principles employed by an expert
 13 are reliable: (1) whether the method “can be (and has been) tested;” (2) whether the
 14 method “has been subjected to peer review and publication;” (3) the method’s “known or
 15 potential rate of error;” (4) whether there are “standards controlling the technique’s
 16 operation;” and (5) whether the method has “general acceptance” within the “relevant
 17 scientific community.” *Daubert*, 509 U.S. at 592–94; accord *Kumho Tire*, 526 U.S. at
 18 149–50. These factors are not exhaustive, and the Supreme Court has emphasized that
 19 the reliability inquiry is “a flexible one.” *Kumho Tire*, 526 U.S. at 149–50. Moreover,
 20 while pretrial Daubert hearings are commonly used, they are certainly not required. *See*
 21 *Barabin*, 740 F.3d at 463–64.

22 23 **III. DISCUSSION**

24 Defendant contends that Mr. Pedersen’s opinions regarding damages are improper
 25 as they rest entirely on an assumption that the FDA would have approved Plaintiffs’ drug
 26 candidate (NP-2), which is speculative, conjectural and is not supported by any accepted
 27 scientific or economic analysis. (Def.’s Daubert Mot. 3, ECF No. 127.) Defendant also
 28 attacks Mr. Pedersen’s assumptions and conclusions regarding the potential market and

1 market share for NP-2. The Court has held a *Daubert* hearing, reviewed all of the parties
2 filings, and has conducted its own review of the *Daubert* factors. As discussed below,
3 the Court finds that these factors favor exclusion of Mr. Pedersen's damages opinion¹.

4 **A. Expert Qualifications**

5 Mr. Pedersen has been appraising the value of companies for more than 30 years.
6 He founded Affiliated Business Appraisers in 1985, through which he provides
7 appraisals of numerous business entities, including intangible assets. As of March 8,
8 2011, he had given expert testimony in over 120 cases. It is clear from his experience
9 that he is an expert on valuing businesses. Indeed, Defendants do not challenge his
10 qualifications as a business valuation expert *per se*.

11 However, Mr. Pedersen's qualifications to opine on the value of a drug patent that
12 derives much of its value on FDA approval has come into question. Although this issue
13 was not explicitly raised in Defendant's motion (Defendant attack Mr. Pedersen's
14 opinion, but not his qualifications), the Court is concerned that Mr. Pedersen does not
15 qualify as an expert in this particular case. This concern arises from the fact that the
16 value of the patent assignment agreement at issue depends completely on whether or not
17 the drug would have been approved by the FDA (the parties agree on the fact that the
18 value of NP-2 hinges on FDA approval). Mr. Pedersen has no experience or expertise
19 with respect to FDA drug approval. He admits that he has no experience dealing with
20 the FDA, no experience getting a drug approved by the FDA, and has no experience in
21 the requisite clinical studies to get a drug approved by the FDA. (Pedersen Depo., 13:2-
22 15:13, 164:18-24, ECF No. 127-1, Ex. B.) Nonetheless, and in light of the fact that the
23 parties have not directly challenged Mr. Pedersen's expertise, the Court finds that it is
24 more helpful to analyze Mr. Pedersen's actual opinions regarding damages instead of his
25

26 ¹ The Court also excludes Mr. Pedersen's opinion testimony regarding
27 commercial reasonableness, breach of contract, and mitigation, as these opinion have
28 been challenged by Defendant as well. (Def.'s *Daubert* Mot. 3.) Plaintiffs have not
opposed this challenge, and therefore are deemed to have admitted that Mr. Pedersen is
not qualified to opine on these topics in this matter.

1 qualifications.

2 **B. Pedersen's Report and Purported Testimony**

3 As an initial matter, the Court notes that it is satisfied that estimating damages in
4 this case, as the loss of royalty income in the amount of 2% per year of NP-2's market
5 share in the relevant market, then discounted due to risk and other relevant factors, is an
6 appropriate method for finding a damages figure. This number must then be calculated
7 in today's dollars, with a present value calculation. This approach is embraced by both
8 experts in this case, and Defendant does not challenge Mr. Pedersen's overall approach
9 to approximating damages. Instead, the Court is concerned with the inputs that Pedersen
10 proposes. In other words, the damages equation itself is not in question; instead, the
11 Court finds that the values of the variables that Mr. Pedersen plugged into the equation
12 are suspect.

13 There are three crucial variables that effect damage calculations in this case: (1)
14 the risk surrounding FDA approval of NP-2, (2) the size of the potential market for NP-2
15 once it has been approved by the FDA, and (3) the market share that NP-2 would have
16 secured. The first is essential because without approval, NP-2 would be worth very
17 little. The second and third are vital because, assuming the drug is approved, the market
18 size and market share directly determine the potential gross profits that NP-2 would have
19 made. As explained below, Mr. Pedersen's opinion regarding these variables is not
20 based on "sufficient facts or data." Fed. R. Evid. 702(b). Moreover, with respect to
21 these variables, Mr. Pedersen has no "scientific, technical, or other specialized
22 knowledge [that] will help the trier of fact to understand the evidence or to determine a
23 fact in issue." Fed. R. Evid. 702(a). Finally, the testimony is unreliable because Mr.
24 Pedersen has no "reliable basis in the knowledge and experience of the relevant
25 discipline." See *Kumho Tire*, 526 U.S. at 149 (internal quotation marks and alterations
26 omitted).

27 **1. Mr. Pedersen's FDA Assumptions and Conclusions**

28 The FDA's Center for Drug Evaluation and Research (CDER) evaluates new

1 drugs before they can be sold. U.S. Food and Drug Administration, *Development &*
2 *Approval Process (Drugs)*, FDA (March 11, 2015),
3 <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm>.² Drug companies
4 like Defendant seeking to sell a drug in the United States must first test it. *Id.* The
5 company then sends the CDER evidence from those tests to prove it is safe and effective
6 for its intended use. *Id.* Once this evidence is submitted, “[a] team of CDER physicians,
7 statisticians, chemists, pharmacologists, and other scientists reviews the company’s data
8 and proposed labeling. If this independent and unbiased review establishes that a drug’s
9 health benefits outweigh its known risks, the drug is approved for sale.” *Id.* This
10 process “is complicated, time-consuming, and costly; the end result is never known at the
11 outset.” U.S. Food and Drug Administration, *The Beginnings: Laboratory and Animal*
12 *Studies*, FDA (March 11, 2015),
13 <http://www.fda.gov/Drugs/ResourcesForYou/ucm143475.htm>. Indeed, the FDA
14 explains that “[l]iterally hundreds, and sometimes thousands, of chemical compounds
15 must be made and tested to find one that can achieve the desirable result without too
16 serious side effects.” *Id.* The FDA also cites estimates by the Pharmaceutical Research
17 and Manufacturers of America that “only 5 in 5,000 compounds that enter preclinical
18 testing make it to human testing, and only 1 of those 5 may be safe and effective enough
19 to reach pharmacy shelves.” *Id.* Another source places the probability of getting a
20 topical drug like NP-2 from Phase I human clinical trials to the U.S. market is around 1
21 in 4. CHRISTOPHER P. ADAMS & VAN V. BRANTNER, BUREAU OF ECONOMICS FEDERAL
22 TRADE COMMISSION, WORKING PAPER NO. 262, NEW DRUG DEVELOPMENT: ESTIMATING
23 ENTRY FROM HUMAN CLINICAL TRIALS 20 (July 7, 2003)(Topical drugs that reach Phase I
24 have a 27% of being approved).

25 It is against this background that Mr. Pedersen assumed *zero* risk of obtaining
26

27 ² The Court takes judicial notice of this source. Fed. R. Evid. 201(b)(2); *see also*
28 *Hansen Beverage Co. V. Innovation Ventures, LLC*, No. 08-CV-1166-IEG, 2009 WL
6597891, at *1.

1 FDA approval. (Pedersen Expert Report 4, ECF No. 127-1, Ex. A.) He also assumed,
 2 that NP-2 would be approved by the FDA in 6 years. (*Id.*) His report makes no
 3 reference to any risks associated with the FDA approval process. When asked how he
 4 came to the conclusion that NP-2 would be approved by the FDA with absolute certainty
 5 he testified as follows:

6 Well, you're not going to have failed clinical trials. You already got ten years
 7 of use on it, years and years of it, beforehand. You're not going to have failure
 8 of clinical trials with this product. It's too valuable of a product. It cures
 9 people's pain where nothing else will do it. You're not going to have a failure
 10 of this product. There's absolutely no basis to come to the conclusion – none
 11 whatsoever – to come to the conclusion that there's any risk that the FDA
 12 would not have approved this product. Not one --- not one idea except some
 13 phantom concern they got over ketamine. They don't have concern over
 14 morphine patches. They don't have concerns over that, but they've got concern
 15 over ketamine stuff. It's ridiculous.

16 (Pedersen Depo. 94:5-25.) Mr. Pedersen is curiously sure of his assumption for someone
 17 who admits to having no experience with the FDA approval process, with getting a drug
 18 approved by the FDA, with actual drug development (apart from managing a pharmacy),
 19 and with preparing, conducting, or submitting clinical studies on drugs to the FDA for
 20 approval. (Transcript of Daubert Hearing at 85:20-22, 85:23-25, 86:21-25, 87:1-6, 87:1-
 21 6, 87:7-9, *Crowley et al. v. EpiCept* (2015) (No. 09-CV-651-MJL).) When asked about
 22 this testimony during the *Daubert* hearing, Mr. Pedersen reiterated that his calculations
 23 were based on the belief that there was zero risk of NP-2 not obtaining FDA approval.
 24 (*Id.* 57:23-58:9.)

25 In fact, Mr. Pedersen testified that he did not consider any statistics concerning the
 26 number of drugs that make it from the pre-clinical stage to human clinical trials after the
 27 approval of an initial new drug application, because these statistics are “totally not
 28 relevant.” (*Id.* 100:11-13.) In support of this claim, he explained that in his research,
 such statistics were not “something that investors considered.” (*Id.* 101:6-24). He
 indicated that these statistics were “uncomparable” to NP-2’s probability of success
 because the statistics do not take into account differences in the drugs. (*Id.*)

Moreover, when breaking down Mr. Pedersen’s claims, it becomes clear that he

1 has relied completely on statements by Dr. Flores to come to his conclusions regarding
2 the certainty of FDA approval, not his own expertise. Mr. Pedersen claims that there
3 would be no issues with approval, because the efficacy and lack of toxicity in NP-2 is
4 not subject to dispute. (Pedersen Depo. 160:18-161:5.) Essentially, he claims that when
5 EpiCept eventually began conducting appropriate clinical trials, the drug would be
6 approved because it was effective and safe. When questioned how he came to this
7 conclusion, he indicated that the efficacy of NP-2 was determined by “various doctors,
8 including Dr. Flores.” (*Id.* 160:21-23.) With respect to the potential toxicity of the drug,
9 Mr. Pedersen testified that Plaintiffs’ observations of their patients who received NP-2
10 treatments did not reveal “side effects” and that NP-2 “didn’t get into the blood.”
11 (*Id.* 161:8-21.) After more questioning, Mr. Pedersen admitted that with respect to
12 clinical studies regarding efficacy and toxicology, that his communications with Dr.
13 Flores were the only source of information regarding the efficacy and toxicology of NP-
14 2. (*Id.* 164:1-10.)

15 During the hearing, Mr. Pedersen suggested that he knew the drug was effective
16 because “he saw patients personally.” (Transcript of Daubert Hearing 107:11.) He
17 testified that he saw “four or five” patients for “moments,” but that the effect of NP-2
18 was “almost immediate.” (*Id.* 109:8-18.) When prompted to explain his understanding
19 of how long the drug lasted, Mr. Pedersen explained that when his daughter had a
20 migraine, “she rubbed it on her forehead, or her temples, and the darn thing went away
21 within minutes. I’m a believer in this drug.” (*Id.* 110:9-11.)

22 The Court finds Mr. Pedersen’s opinion that there was zero risk associated with
23 FDA approval of NP-2 completely unreliable because Mr. Pedersen has no “reliable
24 basis in the knowledge and experience of the relevant discipline.” *See Kumho Tire*, 526
25 U.S. at 149 (internal quotation marks and alterations omitted). His testimony regarding
26 FDA approval is either based on pure conjecture, or simply a parroting of what Dr.
27 Flores told him. This alone prevents him from opining on the probability of NP-2 being
28 approved by the FDA.

1 Moreover, the Court finds that Mr. Pedersen failed to base his opinion regarding
 2 FDA approval on “sufficient facts or data.” Fed. R. Evid. 702(b). Mr. Pedersen refused
 3 to look for any statistics to estimate the risk that the FDA would not approve NP-2,
 4 because he thinks that investors do not consider such things. Instead, he simply assumed
 5 that there was no risk. Such an assumption defies logic given the uncertainty in the FDA
 6 process. Further, it contradicts his own testimony that “risk to the investor is
 7 fundamental in business appraisal.” (Transcript of Daubert Hearing 34:23-25.) The
 8 Court must also exclude Mr. Petersen’s testimony for failing to assign any risk to FDA
 9 approval, and contradicting himself in the process.

10 Apart from his reliance on Dr. Flores regarding the efficacy and safety of NP-2, he
 11 based his opinion on observing a few patients for “moments” and his daughter’s
 12 temporary pain relief. Mr. Pedersen’s observations of NP-2 patients are not sufficient or
 13 reliable data on which to base an expert opinion. While Mr. Pedersen is a highly
 14 qualified business valuator, he is not a medical expert. The Court would be delinquent in
 15 its duty as the gatekeeper for expert testimony if it were to allow such an “opinion” to be
 16 presented to the jury regarding drug efficacy and toxicology.

17

18 2. Mr. Pedersen’s Market and Market Share Assumptions and

19 Conclusions

20 Mr. Pedersen claims that he estimated the size of the market for NP-2 at
 21 \$700,000,000 per year. (Pedersen Expert Report 4.) When asked how he arrived at the
 22 size of the market, he testified that \$700,000,000 was the “minimum size that Peter
 23 Golikov [(former EpiCept President)] estimated.” (Pedersen Depo. 141:9-24.) This
 24 alone make’s Mr. Pedersen’s opinion on market size inadmissible, as it is not based on
 25 his own knowledge and experience regarding potential drug markets.

26 In addition, although Mr. Pedersen attempted to justify his reliance on “Mr.
 27 Golikov’s projection,” he never provided any data on which he actually relied in
 28 formulating the \$700,000,000 figure. (Transcript of Daubert Hearing 64:21-66-23.) Of

1 course, expecting Mr. Pedersen to provide such data would be an insurmountable
 2 obstacle for Mr. Pedersen because he did not formulate the market size figure. Apart
 3 from admitting that he borrowed “Mr. Golikov’s projection,” the fact that Mr. Pedersen
 4 could not identify the geographical region of the market shows he either had nothing to
 5 do with the market size calculation, or relied on a market size of indefinite geographic
 6 scope. (*Id.* 142:8-143:6.) In either situation, his expert opinion on the matter is
 7 inadmissible since it does not rely on “sufficient facts or data.”

8 Mr. Pedersen also assumes that NP-2 will capture the entire relevant market within
 9 4 years of FDA approval. (Pedersen Expert Report 4.) His expert report contains no
 10 analysis of this claim at all, and is properly excluded because it does not rely on any facts
 11 or data.

12 Moreover, Mr. Pedersen admits that he never came to a conclusion regarding NP-
 13 2’s potential market share in his report. (Pedersen Depo. 148:19-149:23.) Instead, he
 14 provided reasons why NP-2 would have more market share than other drugs, and why
 15 NP-2 would add new value to the market. (*Id.*) Therefore, because the Court finds his
 16 opinion that NP-2 would corner the entire market in 4 years is completely unfounded,
 17 this testimony is excluded.

18 19 **C. Plaintiffs’ Estoppel Argument**

20 During the hearing, and in supplemental briefing filed after the hearing, Plaintiffs
 21 argued that “EpiCept made the same arguments challenging the basis of Mr. Pedersen’s
 22 damages, including the issue of FDA approval, in its Motion for Summary Judgment,
 23 and in its Response Brief to the Doctors’ Appeal [(“RB”)].” (Pls.’ Supp. Brief 2, ECF
 24 No. 155; Transcript of Daubert Hearing - Afternoon Session 45:22-46:13.) Plaintiffs
 25 then list a number of arguments that Defendant made regarding damages in its RB that
 26 they also argued during the *Daubert* hearing. (Pls.’ Supp. Brief 2.) Essentially,
 27 Plaintiffs suggest that because these issues were previously addressed in this litigation,
 28 considering these arguments now is improper. Indeed, Plaintiffs assert that the Ninth

1 Circuit found “unequivocally that the Doctors’ three causes of action should go to the
2 jury.” (*Id.* 3.)

3 Even a cursory review of the Court’s summary judgment order and Ninth Circuit
4 mandate show that Plaintiffs’ argument is disingenuous at best. First, the Court’s order
5 granting summary judgment on behalf of Defendant *never* mentions the issue of damages
6 in its analysis, nor does it provide any *Daubert* analysis. In fact, the entire order only
7 uses the word damages twice, when identifying the elements of two separate causes of
8 action. (Order Granting Summ. J. 10, 16, ECF No. 83.) Because the Court did not
9 address this argument at trial, the Ninth Circuit would generally not consider it on
10 appeal. *See Smith v. Marsh*, 194 F.3d 1045, 1052 (9th Cir.1999); *see also In re E.R.*
11 *Fegert, Inc.*, 887 F.2d 955, 957 (9th Cir.1989). Before an argument will be considered
12 on appeal, “the argument must be raised sufficiently for the trial court to rule on it,” or
13 fall within one of the “narrow exceptions” to the general rule that an issue may not be
14 raised for the first time on appeal. *Sofamor Danek Grp., Inc. v. Brown*, 124 F.3d 1179,
15 1186 n. 4 (9th Cir.1997). So, Plaintiffs argument could be saved if Mr. Pedersen’s
16 expected testimony on damages or qualifications had been raised before this Court, even
17 if they were not addressed in the Court’s summary judgment. However, the parties did
18 not brief this issue or otherwise bring it to the court’s attention. (*See* Order Granting
19 Summ J.)

20 Plaintiffs have the help of an exception to this general rule, where the appellate
21 court will still consider an argument not raised in the trial court: (1) there are
22 “exceptional circumstances” why the issue was not raised in the trial court, (2) the new
23 issue arises while the appeal is pending because of a change in the law, or (3) the issue
24 presented is purely one of law and the opposing party will suffer no prejudice as a result
25 of the failure to raise the issue in the trial court. *United States v. Carlson*, 900 F.2d
26 1346, 1349 (9th Cir.1990) (citing *United States v. Rubalcaba*, 811 F.2d 491, 293 (9th
27 Cir.1987); *Bolker v. Comm’r of Internal Revenue*, 760 F.2d 1039, 1042 (9th Cir.1985);
28 *United States v. Patrin*, 575 F.2d 708, 712 (9th Cir.1978)). As none of the exceptions

1 exist in this case, Plaintiffs argument again falls flat.

2 That being said, the appellate court may consider any issue supported by the
3 record, even if the lower court did not consider it. *In re E.R. Fegert*, 887 F.2d at 957. So
4 once again, Plaintiffs argument could be viable if the Ninth Circuit simply addressed the
5 damages and *Daubert* issues in its order. Unfortunately for Plaintiffs, and contrary to
6 their vociferous affirmations to the contrary, the Ninth Circuit *never* mentions this issue
7 in its opinion. (*See* Mandate, ECF No. 90.) In light of this, the Court is frankly
8 astonished that Plaintiffs suggest that “[i]t is clear that the Parties have already litigated
9 the issue of the purported unreliability of Mr. Pedersen’s damages and the higher Court
10 has already ruled.” (Pls.’ Supp. Brief 3.)

11 Plaintiffs’ Counsel is reminded that maintaining the integrity and competence of
12 the legal profession requires candor to the Court and opposing counsel. MODEL RULES
13 OF PROF’L CONDUCT R. 3.1, 3.3, 3.4, 8.4 (2013); CivLR. 83.4(a)(2)(3), 83.4(b). Further
14 frivolous arguments lacking any basis in fact may be met with sanctions. CivLR. 83.1,
15 83.5.

16 **D. Plaintiffs’ Miscellaneous Arguments**

17 **1. The Evidence is Admissible, and the Jury Should Decide How** 18 **Much Weight to Afford It**

19 Plaintiffs argue that expert opinion testimony “should be judged like any other
20 testimony . . . [the jury] may accept it or [] reject it and give it as much weight as [the
21 jury] thinks it deserves” given the witness’s qualifications and explanations. (Transcript
22 of Daubert Hearing - Afternoon Session 44:8-12.) They insist that the challenges made
23 by Defendant here go to the “weight of the evidence,” but do not implicate the Court’s
24 gatekeeping obligation. (*Id.* 46:6-13.)

25 As explained above, the Court is not excluding Mr. Pedersen’s testimony on a
26 whim—indeed the Court has no choice but to exclude the testimony which is either not
27 based on “sufficient facts or data” or not within Mr. Pedersen’s expertise. Moreover,
28 allowing Mr. Pedersen to testify to his “opinion” in front of the jury could lead to unfair

1 prejudice, as the jury could rely heavily on the testimony of “an expert,” even though his
2 underlying assumptions are glaringly inappropriate.

3 **2. If the Court Excludes the Evidence, it Eviscerates Plaintiffs’ Case**

4 The Court is unconcerned with Plaintiffs’ claim that excluding this expert is “in
5 effect throwing out the entire lawsuit of my clients who have been waiting for their
6 chance in court for many, many years.” (Transcript of Daubert Hearing - Afternoon
7 Session 46:20-24.) This argument is irrelevant and fails to acknowledge that the Court
8 must conduct a *Daubert* inquiry and exclude an unqualified expert; the Court cannot
9 allow an expert to testify just because exclusion of his or her testimony would eviscerate
10 Plaintiffs’ case.

11 Moreover, the “expert” here relied directly and without any investigation on
12 assertions by witnesses that are due to testify at trial. Thus, despite Plaintiffs’ counsel’s
13 suggestion that exclusion destroys her clients entire case, the Court is not convinced. In
14 fact, the Court alluded to this during the *Daubert* hearing. (Transcript of Daubert
15 Hearing 97:10-14 (Judge Lorenz explained that if Mr. Pedersen “is relying 100 percent
16 on Dr. Flores and Dr. Crowley, why do [Plaintiffs] need him. I mean, [Mr. Pedersen has]
17 already said that if the jury doesn’t believe [the doctors when they testify], then why
18 should they believe him.”).) Plaintiffs appear to have caught on. (Pls.’ Second Supp.
19 Brief 2, ECF No. 157 (“Ms. Larson wishes to clarify that the [Plaintiffs] intend to
20 proceed with trial notwithstanding the Court’s [potential] decision [to exclude Mr.
21 Pedersen] in that the Appellate decision confirmed the Doctors’ right to rescission, . . .
22 and the Doctors are fully prepared and qualified to testify to the value of their patent as
23 the Court noted.”))

24 **3. The Parties Used the \$700,000,000 As a Basis for their** 25 **Negotiations and Defendant is Now Impeaching its Own Contract**

26 Plaintiffs also seems to suggest that Defendant may not challenge the FDA
27 approval timetable Mr. Pedersen presents in his report, because the parties relied on
28 these factors during the negotiations of the underlying assignment agreement.

(Transcript of Daubert Hearing 96:10-22.) Essentially they suggest because Defendant agreed to a timetable for FDA approval in the agreement, they must stipulate that they breached the agreement before they can challenge that such a timetable was appropriate. This argument misses the mark as Defendants are challenging Mr. Pedersen's FDA approval assumptions. Even if Mr. Pedersen based his assumptions on explicit terms in the contract, his testimony would not be admissible without more, because it would not be based on sufficient data and facts and would not be based on any expertise he had regarding FDA approval. If anything, it would be evidence of the parties' expertise in the area, as discussed above.

4. The Motion is Untimely

Plaintiffs have repeatedly referenced the fact that Defendant's motion was somehow untimely. The Court reminds Plaintiffs that this *Daubert* challenge could have come during trial, even after the expert testimony was presented, and Defendants would still have been within their rights to request the court performing its "gatekeeping" role. If Plaintiffs are seriously concerned with being surprised by this motion, or not having enough time to prepare, they should consider themselves fortunate that the Court required briefing of this issue before trial.

5. Granting this Motion Will Set Poor Precedent

Plaintiffs also contend that "if this *Daubert* challenge survives, then no business expert could ever prevail. None. Because you would apply a standard that is not found in any court in any case cited by anyone in this courtroom or anywhere." (Transcript of Daubert Hearing - Afternoon Session 45:3-13.) Ignoring the hyperbolic nature of this statement, the Court finds the substantive claim of setting a poor precedent dubious. There are surely people who are intimately familiar with the FDA process and drug patent valuation; Plaintiffs could certainly have hired an FDA expert to opine to the variables that Mr. Pedersen simply glossed over and assumed to be true. In fact, it appears that Drs. Flores and Crowley and Mr. Golikov know a great deal more on the


1 subject then Mr. Pedersen does. Moreover, contrary to Plaintiffs position³, Defendant's
 2 expert does present an argument regarding a FDA approval risk discount factor of 20%,
 3 and they support this claim with reasoned analysis based on empirical research.
 4 Therefore, Plaintiffs have no basis to suggest that doing this was impossible for Mr.
 5 Pedersen, or would preclude any other business valuation expert from making basic
 6 inquiries into the risk involved in FDA approval.

7 **IV. CONCLUSION**

8 In light of the foregoing, Mr. Pedersen's testimony and expert report are excluded
 9 from trial.

10 **IT IS SO ORDERED.**

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 12 DATED: March 11, 2015

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 14 M. James Lorenz
 15 United States District Court Judge
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23
 24 ³Plaintiffs' counsel Ms. Larson insists that Defendant is holding Mr. Pedersen to a double
 25 standard. To wit, Ms. Larson argues that Defendant is suggesting that Mr. Pedersen should have
 26 done independent analysis that Defendant's expert did not do. (Transcript of Daubert Hearing -
 27 Afternoon Session 42:16-21.) This position demonstrates Ms. Larson's lack of a basic
 28 understanding of Defendant's expert Mr. Kennedy's supplemental expert report, in which he
 does precisely what Ms. Larson says is impossible—he provides some assessment of the risk
 associated with FDA approval. (Kennedy Supp. Expert Report 8, ECF No. 111-2.) This risk
 assessment provided by Mr. Kennedy also contradicts Ms. Larson's absolute claim that
 Defendants "have proffered no data that would be different upon which a business valuator
 would rely." (*Id.* 38:25-39:2.)